

What is claimed is:

1. A method for determining bcr-abl translocation rearrangements in a biological sample comprising the steps of:

- a) extracting RNA from a biological sample;
- b) quantifying the extracted RNA;
- c) reverse transcribing the RNA to cDNA;
- d) amplifying the cDNA and detecting a cDNA signal by using the primers

and probes set forth in SEQ. ID. NOS. 1-8;

e) obtaining a standard curve of cDNA signals from serial dilutions of a leukemic cell line, wherein the cDNA is obtained by repeating steps a) - d) with the RNA from the leukemic cell line and not the sample; and

f) extrapolating a measurement of the leukemic cells present in the sample by comparing the signal from step d) with that from step e).

2. The method of claim 1 wherein the amplification and detection of the cDNA in step d) is accomplished by Real Time PCR.

3. The method of claim 1 wherein the amplification and detection of the cDNA in step e) is accomplished by Real Time PCR.

4. The method of claim 1 wherein the measurement in step f) comprises a measurement of the number of leukemic cells present in the sample, wherein a result of less than a certain number of cells is reported as negative, and a result of more than a certain number is reported as positive.

5. The method of claim 4 wherein wherein a result of less than one leukemic cell per ten thousand total cells is reported as negative, and a result of more than one leukemic cell per ten thousand total cells is reported as positive.

6. The method of claim 1 wherein the measurement in step f) comprises a

measurement of the total number of leukemic cells present in the sample.

7. The method of claim 1 further comprising the step of running the cDNA PCR products of step d) on an electrophoretic gel to obtain fragment size and hence identity information.

8. The method of claim 1 wherein the amplification and detection of the cDNA in step d) is performed in a single container.

9. The method of claim 1 wherein the amplification and detection of the cDNA in step e) is performed in a single container.

10. A method of diagnosing CML or ALL by performing the assay of claim 1.

11. A method of diagnosing CML or ALL by performing the assay of claim 7.

12. The method of claim 1 wherein the sample includes an RNase inhibitor.

Add p2